

# PRO 2000



## Drug Description

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PRO 2000 is a naphthalene sulfonic acid polymer. The polymer is polyanionic and consists of alternating 2-naphthalene sulfonic acid sodium salt and methylene units. [1]

## HIV/AIDS-Related Uses

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PRO 2000 is an antimicrobial vaginal gel being investigated for the prevention of HIV and other sexually transmitted diseases.[2]

## Non-HIV/AIDS-Related Uses

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In laboratory tests and in animal studies, PRO 2000 demonstrated activity against Chlamydia trachomatis, gonorrhea neisseriae, and herpes simplex virus.[3]

Though not spermicidal, PRO 2000 has some contraceptive activity in animals; its contraceptive efficacy is dose-dependent.[4]

## Pharmacology

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PRO 2000 binds to CD4 with nanomolar affinity and blocks CD4 binding to HIV gp120. It inhibits infection by a wide range of HIV isolates in a variety of cell types.[5]

Following topical administration of naphthalene 2-sulfonate polymer to animals and intravaginal application in humans, no systemic absorption was detected.[6]

## Adverse Events/Toxicity

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In Phase I clinical trials, PRO 2000 was safe and well-tolerated. Side effects were generally mild and infrequent and included vulvovaginal ulceration, irritation, itching, burning, and bleeding. Pain on passing urine was also reported.[7]

In a trial of 63 sexually active HIV uninfected women and abstinent HIV infected women, no serious adverse events were reported. Seventy-three percent of participants experienced at least one adverse event, of which 82% were

classified as mild.[8]

In a second trial of 73 HIV uninfected abstinent women, three women developed cervical abrasion. In both trials, the 0.5% gel formulation was better tolerated than the 4% gel formulation.[9]

## Drug and Food Interactions

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No drug or food interactions are reported with PRO 2000. The product is compatible with latex condoms.[10]

## Clinical Trials

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For information on clinical trials that involve PRO 2000, visit the ClinicalTrials.gov web site at <http://www.clinicaltrials.gov>. In the Search box, enter: PRO 2000 AND HIV Infections.

## Dosing Information

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Mode of Delivery: Intravaginal.[11]

Dosage Form: The investigational product is an aqueous gel formulation containing 2% or 4% naphthalene 2-sulfonate polymer.[12] Non-active ingredients include a synthetic carbomer gelling agent (Carbopol 1382), lactic acid, trolamine, methylparaben, propylparaben, and sodium benzoate. The product is buffered to pH 4.5.[13]

Storage: Store at 15 to 30 C (59 to 86 F) and protect from light.[14]

## Chemistry

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CAS Name: 2-Naphthalenesulfonic acid, sodium salt, polymer with formaldehyde[15]

CAS Number: 29321-75-3[16]

Molecular weight: Approximately 5000 kilodaltons[17]

Physical Description: The active ingredient of PRO 2000 is a light brown solid.[18]

Stability: Manufacturer data indicate that PRO

# PRO 2000



## Chemistry (cont.)

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2000 is stable at 40 C and 75% relative humidity for 12 months.[19]

Solubility: Highly water-soluble (approximately 1gm/5ml).[20]

## Other Names

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Naphthalene 2-sulfonate polymer[21]

Formaldehyde-sodium 2-naphthalenesulfonate polymer[22]

PRO 2000/5[23]

Sodium 2-naphthalenesulfonate-formaldehyde polymer[24]

## Further Reading

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Mayer KH, Karim SA, Kelly C, Maslankowski L, Rees H, Profy AT, Day J, Welch J, Rosenberg Z; HIV Prevention Trials Network (HPTN) 020 Protocol Team. Safety and tolerability of vaginal PRO 2000 gel in sexually active HIV-uninfected and abstinent HIV-infected women. AIDS. 2003 Feb 14;17(3):321-9.

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## Manufacturer Information

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PRO 2000  
Indevus Pharmaceuticals, Inc.  
99 Hayden Avenue, Suite 200  
Lexington, MA 02421

## For More Information

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Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET

- Via Live Help: [http://aidsinfo.nih.gov/live\\_help](http://aidsinfo.nih.gov/live_help) Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET

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